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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,720	11/07/2001	William M. Bonner	214041	1857

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[REDACTED] EXAMINER

CHAKRABARTI, ARUN K

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1634

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>10/045,720</b>	Applicant(s) <b>Bonner</b>
	Examiner <b>Arun Chakrabarti</b>	Art Unit <b>1634</b>
		
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
<b>Period for Reply</b> A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>		
<b>Status</b> <p> <input checked="" type="checkbox"/> 1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Nov 7, 2001</u> </p> <p> 2a) <input type="checkbox"/> This action is FINAL.      2b) <input checked="" type="checkbox"/> This action is non-final. </p> <p> 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213. </p>		
<b>Disposition of Claims</b> <p> 4) <input checked="" type="checkbox"/> Claim(s) <u>27-33</u> is/are pending in the application. </p> <p> 4a) Of the above, claim(s) _____ is/are withdrawn from consideration. </p> <p> 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. </p> <p> 6) <input checked="" type="checkbox"/> Claim(s) <u>27-33</u> is/are rejected. </p> <p> 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. </p> <p> 8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement. </p>		
<b>Application Papers</b> <p> 9) <input type="checkbox"/> The specification is objected to by the Examiner. </p> <p> 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). </p> <p> 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action. </p> <p> 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner. </p> <p> <b>Priority under 35 U.S.C. §§ 119 and 120</b> </p> <p> 13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). </p> <p> a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:  1. <input type="checkbox"/> Certified copies of the priority documents have been received.  2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.  3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). </p> <p> *See the attached detailed Office action for a list of the certified copies not received. </p> <p> 14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. </p> <p> 15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. </p>		
<b>Attachment(s)</b> <p> 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) </p> <p> 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) </p> <p> 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>0803</u> </p> <p> 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ </p> <p> 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) </p> <p> 6) <input checked="" type="checkbox"/> Other: <i>Detailed Action</i> </p>		

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## **DETAILED ACTION**

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 27-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,362,317 in view of Stratagene Catalog (page 39, 1988).

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This rejection is based on the fact that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Therefore, in this case, the intended use of determining double-stranded breaks has no been given any patentable weight.

Claims 1-10 of U.S. Patent No. 6,362,317 clearly teaches the isolated or purified antibody that binds to a C-terminal amino acid sequence of an H2A histone protein, the C-terminal amino acid sequence consisting of SQ(D/E/A)(I/L/F) (SEQ ID NO: 1) and a means of facilitating detection of binding of the antibody to an H2A histone protein.

Claims 1-10 of U.S. Patent No. 6,362,317 do not teach the combination of antibodies and a means of facilitating detection of binding of the antibody in the form of a kit.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39). It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the isolated or purified antibody that binds to a C-terminal amino acid sequence of an H2A histone protein, the C-terminal amino acid sequence consisting of SQ(D/E/A)(I/L/F) (SEQ ID NO: 1) and a means of facilitating detection of binding of the antibody to an H2A histone protein, as taught by Claims 1-10 of U.S. Patent No. 6,362,317, into

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a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is "quality control" (page 39, column 1).

### ***Conclusion***

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

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Arun Chakrabarti,

Patent Examiner,

September 11, 2003



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SUPERVISORY PATENT EXAMINER  
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